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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,136	06/07/2001	Michael G. Walker	PB-0003 USN	5258
27904	7590	09/23/2002		
INCYTE GENOMICS, INC. 3160 PORTER DRIVE PALO ALTO, CA 94304			EXAMINER	
			MOORE, WILLIAM W	
		ART UNIT	PAPER NUMBER	
		1652	10	
DATE MAILED: 09/23/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/786,136	WALKER ET AL.
	Examiner William W. Moore	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8 and 11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not 5 so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

10 Group I, claims 1-8 and 11, drawn, in part, to a first product, a polynucleotide encoding a polypeptide coexpressed with a gene encoding a neurotransmitter-processing associated polypeptide, to a first method of making utilizing the first product, and vectors and host cells comprising same, in recombinant production of a polypeptide coexpressed with a gene encoding a neurotransmitter-processing associated polypeptide, the coexpressed polypeptide, compositions comprising both, and a first method of use of the encoding nucleic acid sequence in treating a disease or medical condition.

15 Group II, claims 1, 2 and 10, drawn to a second product, a hybridization probe capable of hybridizing to polynucleotides encoding a neurotransmitter-processing associated polypeptide and to a first method of use of the second product in diagnostic assay to detect a disease or condition associated with altered expression of a gene co-expressed with a gene encoding a neurotransmitter-processing associated polypeptide.

20 Group III, claim 9, drawn, in part, to a third product, an antibody to a neurotransmitter-processing associated coexpressed polypeptide having the amino acid sequence of SEQ ID NO:6.

25 Group IV, claim 9, drawn, in part, to a genus of fourth products, antibodies to any peptide comprising six sequential amino acids within a neurotransmitter-processing associated coexpressed polypeptide having the amino acid sequence of SEQ ID NO:6.

The inventions of Groups I and II are not so linked as to form a single general inventive concept because a hybridization probe of Group II is not required to have the coding capacity of an integral polynucleotide of Group I, and indeed may have but a fraction of its nucleotide sequence, thus lacks the special technical feature of the invention 30 of Group I, and because practice of methods of Groups I and II are mutually exclusive, thus share no same or corresponding a special technical feature.

Inventions of Group I and of Groups III and IV are not linked as to form a single general inventive concept because the compounds of Groups III and IV are structurally and functionally unrelated to the compounds of Group I and have different modes of operation and effects than the compounds of Group I, thus inventions of Group I and of 35 Groups III and IV lack a same or corresponding special technical features.

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Inventions of Group II and of Groups III and IV are not linked as to form a single general inventive concept because the polypeptides of Groups III and IV are structurally and functionally unrelated to the polypeptides of Group II and have different modes of operation and effects than the polypeptides of Group I, thus inventions of Group II and of Groups III and IV lack a same or corresponding special technical features.

Inventions of Group III and of Group IV are not linked as to form a single general inventive concept because the antibodies of Groups III and IV need have neither a common mode of operation nor similar effects where an antibody raised to a hexapeptide of SEQ ID NO:6 may be incapable of recognizing the secondary or tertiary structure of the same hexapeptide present in the integral polypeptide of SEQ ID NO:6, conversely an antibody raised to the integral polypeptide of SEQ ID NO:6 may be incapable of recognizing the secondary structure of any individual hexapeptide present in another polypeptide, thus inventions of Group III and IV need share no same or corresponding special technical feature.

This application contains claims directed to more than one species of the generic inventions of Groups I and II. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. A neurotransmitter-processing associated coexpressed polynucleotide of SEQ ID NO:1, an encoded polypeptide, compositions comprising either, and methods of making and use thereof.
2. A neurotransmitter-processing associated coexpressed polynucleotide of SEQ ID NO:2, an encoded polypeptide, compositions comprising either, and methods of making and use thereof.
3. A neurotransmitter-processing associated coexpressed polynucleotide of SEQ ID NO:3, an encoded polypeptide, compositions comprising either, and methods of making and use thereof.
4. A neurotransmitter-processing associated coexpressed polynucleotide of SEQ ID NO:4, an encoded polypeptide of SEQ ID NO:6, compositions comprising either, and methods of making and use thereof.
5. A neurotransmitter-processing associated coexpressed polynucleotide of SEQ ID NO:5, an encoded polypeptide, compositions comprising either, and methods of making and use thereof.

The claims are deemed to correspond to the species listed above in the following manner:

- A. Claims 1-8 and 11 are generic for the five species of integral polynucleotides of SEQ IDs NOs:1-5 and their integral encoded polypeptides.

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B. Claims 1, 2 and 10 are generic for the five subgenera of oligonucleotide and polynucleotide probes that may be defined by the nucleic acid sequences of SEQ IDs NOs:1-5.

5 The species of Group I listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each polynucleotide among SEQ IDs NOs:1-5 has an entirely unrelated coding capacity, thus are not so linked as to form a single general inventive concept where they fail to share such a same or corresponding special technical feature.

10 The species of Group II listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each probe that might be defined by one nucleic acid sequence among SEQ IDs NOs:1-5 cannot be used to detect other nucleic acid sequences among SEQ IDs NOs:1-5, thus are not so linked as to 15 form a single general inventive concept where they fail to share such a same or corresponding special technical feature.

20 If Applicant elects an invention of Group I or of Group II, Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Because claim 1 explicitly requires that polynucleotide be a "gene", clause (d) of claim 25 2 which describes the invention of Group II above cannot be considered to be properly linked to polynucleotides having coding capacities, genes, of Group I. Thus the restriction requirement between inventions of Groups I and II and the species of Groups A and B is not subject to nonallowance of the linking claim, claim 1. Upon allowance of the linking claim, the restriction requirement as to the linked inventions and species shall not be withdrawn and claims depending from or otherwise including all the limitations of the 30 allowable linking claim will not be entitled to examination in the instant application. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Ms. Lynn E. Murphy on July 7, 2002, a provisional election was made with traverse to prosecute the invention of the species, 35 species 4 above, of coexpressed polynucleotide of the integral SEQ ID NO:4 and its

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encoded polypeptide of SEQ ID NO:6, of Group I, comprising claims 1-8 and 11. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 1-8 and 11 herein are examined to the extent that they describe Applicant's elected species and claims 9 and 10 are withdrawn from further consideration by the
5 examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under
10 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture,
15 or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 and 11 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

A claimed invention must possess a specific, substantial and credible *in vitro* or *in vivo* utility. It is agreed that SEQ ID NO:6 encodes a polypeptide expressed by human nerve
20 cells contemporaneous with the expression by those cells of neurotransmitter-processing enzymes. No prior art polypeptide having a known, or even a proposed, function has any significant degree of amino acid homology with the polypeptide of SEQ ID NO:6, i.e., it shares less than 10% sequence identity with prior art proteins for which a function has at least been proposed. The specification, and the prior art made of record with Applicant's
25 Information Disclosure Statement, Paper NO. 8 filed July 10, 200, are silent as to the *in vivo* function of the polypeptide of SEQ ID NO:6. The specification states no specific *in vitro* utility for the polypeptide of SEQ ID NO:6, and indicates no specific *in vitro* utility for a nucleic acid encoding the polypeptide of SEQ ID NO:6. While Applicant suggests at page 25 of the specification that the nucleic acid sequence of SEQ ID NO:4 has "about
30 58% sequence identity [over 1,062 of its nucleotides] with the gene which encodes the human heavy neurofilament subunit, NF-H (g35028), a homolog to intermediate filament

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(IF) proteins", this relationship was not apparent in the search results. Applicant is invited to make of record the comparison the specification cites, but it is not clear that establishing the similarity will establish any particular function of the polypeptide of SEQ ID NO:6. The closest publications to date of related amino acid sequences, subsequently disclosed in 5 translations of the EMBL database entries Q9BVH8, Q9GMT9, and Q9GKV4 made of record herewith, assign no particular structural class, or functional roles, to the related human and monkey polypeptides three years after Applicant's priority date, at a time where many more potential structural comparisons were available to suggest a function.

Whether the gene and its product have any role at all in regulation of neurotransmitter 10 gene expression, in processing any neurotransmitter, in modulating cellular response to any neurotransmitter, or in any other cellular process, cannot be determined on the basis of the specification and the prior art disclosures. A method of use of a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". 15 *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The specification teaches, pages 20-25, that a mRNA encoding the polypeptide of SEQ ID NO:6 is associated with the presence of mRNAs encoding one or more neurotransmitter enzymes in cells of paraganglionic tumor tissue, and no more. The specification suggests, page 2, the polypeptide of SEQ ID NO:6 might be involved in any among a plethora of diseases 20 and disorders of the nervous system. While any one of the many diseases or disorders is a substantial occurrence, mere allegations of a prospective, potential, utility cannot rise to the level of a **credible** assertion of a **specific** *in vivo* utility that is substantial. Indeed, the specification's diffuse assertions indicate the contrary, that Applicant knew no specific utility for the claimed invention at the time the application was filed that would permit an 25 immediate use by the public of the polypeptide of SEQ ID NO:6 or a nucleic acid that

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encodes it. To address this rejection as it applies to claims 1-6, Applicant is invited to establish a **specific** utility for a nucleic acid encoding the polypeptide of SEQ ID NO:6 or, alternatively, for the encoded polypeptide, and to show that this specific utility is substantial. Claims 7, 8 and 11 drawn, respectively, to pharmaceutical compositions comprising the encoding nucleic acid sequence, to pharmaceutical compositions comprising the encoded polypeptide, and to a method of treating no particular disease or medical condition by administering a pharmaceutical composition comprising the encoding nucleic acid sequence, all present the further issue of a credible application.

Claim Rejections - 35 USC § 112

10 The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claims 1-8 and 11 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a **specific** asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

20 *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8 and 11 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

30 The specification fails to exemplify or describe the preparation of the subject matters of claims 7, 8 and 11. Where the specification fails to identify, exemplify, describe, or even suggest, the biological role of the polypeptide of SEQ ID NO:6, or a nucleic acid

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sequence encoding it, it cannot describe the preparation pharmaceutical compositions comprising these compounds, or a method of use of a compound comprising a nucleic acid sequence encoding the polypeptide of SEQ ID NO:6 in treating any conceivable disease or medical condition. "While one does not need to have carried out one's invention before 5 filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. §112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The specification nowhere furnishes a relevant biological role for the polypeptide of SEQ ID NO:6, or a nucleic acid sequence encoding it, nor does it provide any characteristic 10 permitting a correlation between either of these products and any of the myriad of disease states listed at page 2 of the specification. The Court of Appeals for the Federal Circuit held that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might 15 achieve if one had made that invention". *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Nothing demonstrates that, at the time the specification was filed, Applicant was "able to envision" enough of the role 20 of either product to provide the public with identifying "characteristics [that] sufficiently" permit their use. *Fiers*, 25 USPQ2d at 1604 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)). The specification's treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the biological roles of the products comprised by the claimed pharmaceutical compositions or claimed methods of use thereof.

25 Claims 7, 8 and 11 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for designing a nucleic acid sequence encoding the polypeptide having the amino acid sequence set forth in SEQ ID NO:6, and for preparing the encoded polypeptide,

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5 does not reasonably provide enablement for a preparing a pharmaceutical composition comprising either product nor enablement for a method of use of such a pharmaceutical composition in treating any disease or medical condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 7, 8 and 11 contemplate arbitrary formulation of pharmaceutical compositions where there is no description or suggestion as to how and where such compositions should be administered, nor any description or suggestion of any target cells or tissues, nor any description or suggestion of a specific disease or medical condition that such compositions 10 might have any effect on. Indeed, neither the prior art made of record herewith nor Applicant's specification can identify, taken together, the biological function of compounds of either composition. It is well settled that 35 U.S.C. §112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an 15 attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (recognizing and applying the "Forman" factors). Cf., *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (citing eight factors relevant to analysis of enablement). Applying the "Forman" factors discussed in *Wands*, 20 *supra*, to Applicant's disclosure, it is apparent that:

- a) the specification lacks any specific guidance for determining what role the polypeptide having the amino acid sequence of SEQ ID NO:6 has in a cell or in a tissue,
- 25 b) the specification lacks working examples wherein a polypeptide having the amino acid sequence of SEQ ID NO:6, or its encoding nucleic acid sequence is formulated in any pharmaceutical composition or administered to treat any disease or medical composition,
- c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such formulation or administration, and,
- 30 d) unpredictability exists in the art where no similar polypeptide has been identified nor a biological function determined for distantly-related polypeptides.

Cancellation of the claims 7, 8 and 11 will avoid this rejection.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

5 A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Schalling et al., European Neuropsychopharmacology, 1991, Vol. 1, pages 173-176, made of record with Applicant's Information Disclosure Statement.

Schalling et al., cited in the International Preliminary Examination Report for

15 Applicant's corresponding PCT application, disclose, see Figure 1, coexpression of genes that encode phenylethanolamine N-methyltransferase [PNMT] and tyrosine hydroxylase [TH], the latter a gene recited in claim 1. Since a PNMT-encoding cDNA had previously been isolated in order to prepare the hybridisation probe used by Schalling et al., their disclosure of PNMT gene coexpression inherently anticipates the subject matter of claim 1.

20 Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Wessel et al., Molecular Brain Research, 1992, Vol. 15, pages 349-360, made of record with Applicant's Information Disclosure Statement.

Wessel et al., cited in the International Preliminary Examination Report for Applicant's corresponding PCT application, disclose, see Figure 2, the coexpression of genes encoding 25 both tyrosine hydroxylase and dopamine-beta-hydroxylase, which genes are recited in claim 1, together with a gene encoding phenylethanolamine N-methyltransferase. Since a PNMT-encoding cDNA had previously been isolated in order to prepare the hybridisation probe used by Wessel et al., their disclosure of PNMT gene coexpression inherently anticipates the subject matter of claim 1.

30 Claims 1 and 3 are rejected under 35 U.S.C. §102(b) as being anticipated by Yamada et al., Histochemistry, 1992, Vol. 97, pages 201-206, made of record with Applicant's Information Disclosure Statement.

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Yamada et al., cited in the International Preliminary Examination Report for Applicant's corresponding PCT application, disclose, see Figure 1, the coexpression of genes encoding tyrosine hydroxylase, as recited in claim 1, and phenylethanolamine N-methyltransferase and further disclose, Figure 2, the presence of both the coexpressed 5 PNMT and TH polypeptide products by immunohistochemical procedures. Since a PNMT-encoding cDNA had previously been isolated in order to prepare the hybridisation probe used by Yamada et al., and since a PNMT polypeptide had previously been isolated to prepare the anti-PNMT antiserum of Yamada et al., their dual disclosures of PNMT gene coexpression inherently anticipate the subject matters of claims 1 and 3.

10 Claims 1 and 3 are rejected under 35 U.S.C. §102(b) as being anticipated by Zellmer et al., *The Journal of Neuroscience*, 1995, Vol. 15, pages 8109-8120, made of record with Applicant's Information Disclosure Statement.

Zellmer et al., cited in the International Preliminary Examination Report [IPER] for Applicant's corresponding PCT application, disclose, see Figure 1 and discussion at pages 15 8111-8115, the isolation of a polynucleotide transcript of the gene encoding the homeobox protein Arix expressed together with the dopamine-beta-hydroxylase [DBH] gene, anticipating the subject matter of claim 1, which does not exclude coexpression of its enumerated genes. Zellmer also disclose the encoded amino acid sequence of the Arix transcript, inherently anticipating the subject matter of claim 3.

20 *Conclusion*

Claims 2, 4-8 and 11 are free of the prior art of record to the extent they describe the elected, integral, nucleic acid sequence of SEQ ID NO:4, nucleic acid sequences that are isocoding therewith, complements thereof, the encoded polypeptide of SEQ ID NO:6, compositions comprising either the nucleic acid sequence, its complement, or the encoded 25 polypeptide and methods of use of a composition comprising the nucleic acid sequence in treating diseases or medical conditions because sequence searches conducted in published nucleic acid sequence databases with the nucleic acid sequence of SEQ ID NO:4, as well as

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searches conducted against published amino acid sequence databases with the nucleic acid sequence of SEQ ID NO:4, reveal no remotely similar polypeptide products in the prior art and only a single, marginally related, polynucleotide product in the prior art.

- 5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 7:00AM-5:30PM EST on Mondays and Wednesdays, between 7:00AM-1:30PM EST on Tuesdays and Thursdays, and between 8:30AM and 5:00PM EST on Fridays. The examiner's direct
10 FAX telephone number is 703.746.3169. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or
15 relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
September 19, 2002



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